

A restart from zero. There is no greater reward for developers than to contribute to lifesaving

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Rapid in-vitro diagnostic (IVD) kit for identification of bacteria

Sepsis – a life-threatening disease posing severe systemic symptoms that is caused by a pathogen entering the blood stream in the human body. More than anything, lifesaving is a fight against time. While the conventional method to identify the infecting bacteria often takes 2-3 days, a new method has been developed that drastically reduces the time down to about 5 hours. The person striving to produce this “Rapid in-vitro diagnostic (IVD) kit for identification of bacteria” is Osamu Yasui.

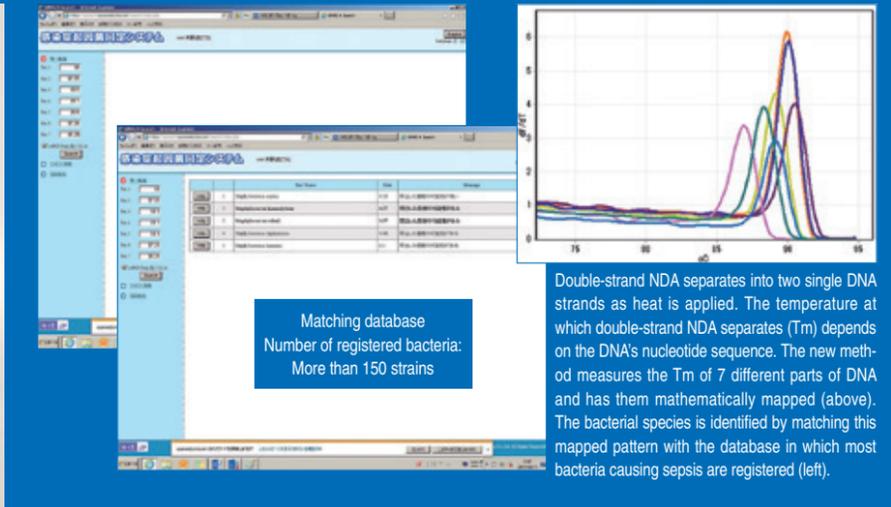
People’s precious lives are protected by many people – from medical doctors and nurses to family members and relatives. The ones who also play an important role are the people in the medical industry who are engaged in the development of the medicine, medical devices and clinical testing tools.

Osamu Yasui, whose goal is to commercialize the “Rapid in-vitro diagnostic (IVD) kit for identification of bacteria”, which identifies the causative bacteria of sepsis, is one of these people.

When asked about the moment he was proud to be a developer, “It was when I heard from a person at a medical institution that a newborn’s life had been saved with this method. I felt deeply rewarded and proud to be working on this project”, he replied. “Although we are still at the stage of clinical research and our kit is the research reagent under development, the fact of having saved a life of a person, regardless of age, reminds me of the value and the responsibility of this project.”

Reducing Testing Time from 2-3 days to about 5 hours

Sepsis is a severe inflammatory condition responding to the pathogen entering the blood stream from the infected area, such as the through the lungs by pneumonia. When people lose their lives due to multiple organ failure, the cause in many cases is sepsis. Despite recent advancements in medical technology, sepsis still has a high mortality



rate. One of the challenges is in the clinical testing practice to identify the infecting bacteria. A blood culture is normally used, but this method requires 2-3 days to get the testing result. Meanwhile, the patient’s condition gets worse, and the mortality rate is said to increase by 8% per hour.

In order to solve this problem, Hideki Niimi, Associate Professor at Graduate School of Medicine and Pharmaceutical Science University of Toyama, Japan, developed a new rapid method to identify the bacteria by checking its DNA. DNA usually exists in a form of two strands tangled together, and if heat is applied, the tangled strands separate into single strands. The temperature at which double-strand DNA separates (called melting temperature: Tm) depends on the DNA’s nucleotide sequence that characterizes the bacteria. Niimi’s method measures the Tm of seven different parts of DNA, and compares with the master data in the database. In this method, the infecting bacteria can be identified in about five hours. This test requires only a small volume of blood, and therefore it benefits infants and the elderly by reducing the burden on their bodies.

Mitsui Chemicals received the license of this technology from the University of Toyama in early 2012. In April in the same year, Mitsui Chemicals officially started the project for the development of the IVD kit for rapid identification of bacteria.

“We started from zero”, Yasui recalled, “We didn’t know what we needed to know.” There

was a reason for this.

Mitsui Chemicals used to have a pharmaceutical group, but sold the business, including many staff with expertise, to a pharmaceutical company in the year of 2000. This tough decision was made when the pharmaceutical industry was intensifying the competition.

He said, “We used to have the technology and know-how related to pharmaceuticals and diagnostics. However, we lost all of it from that point.”

Re-starting with biotechnology

It was fortunate, however, that the company still possessed strength in biotechnology. For example, the enzyme technology for amino acid production, and the plant cell culture technology for manufacturing of chemicals at Hokkaido Mitsui Chemicals, have been inherited within the research groups.

“This project started with this background in biotechnology, including DNA recombination”, said Yasui, “But it was totally a new business and a real challenge for Mitsui Chemicals.”

What is the hard part in commercializing the

clinical testing kit? Yasui answered, “Assuming all the possible cases, and to guarantee the quality of the commercialized product. We also need further development of technology to enable to identify the causative bacteria in a simple manner with high accuracy.”

This issue frequently encountered at this site of the clinical lab is the contamination of foreign substances. “Though our work with the medical institutions, we have experienced that the contamination tends to occur if the lab control is not sufficient,” said Yasui, “Therefore, we are now selling a research-use-only sample with on-site technical support.” He plans to obtain the regulatory approval in 2019 in Japan, and commercialize the IVD kit for rapid identification of bacteria.

“I believe that a job that contributes to medical care is valuable. It is not limited to widely promoting the use of this kit, but also includes developing new diagnostic kits.” The IVD kit for rapid identification of bacteria is positioned as one of the items expected to drive the growth of Mitsui Chemicals’ life science business. 

There is a strong need in the world for the IVD kit a rapid identification of bacteria.

The University of Toyama invented a new testing method, called Tm Mapping, and Mitsui Chemicals is developing the IVD kit for commercialization. “Selling the IVD kit only in Japan is not enough in terms of business. We need to do sales world-wide.” Yasui envisions a scenario including the overseas market. The next big challenge is “to develop a fully automated machine for this IVD kit.”